

REMARKS

I. Status of Claims

Claims 14-31, 33-57 are pending. Claims 14-31, 33-35 and 50-57 have been withdrawn in view of the November 2, 2004, Restriction Requirement. Claims 1-13 and 32 have been cancelled without prejudice or disclaimer of the claimed subject matter. Claim 36 has been amended to further define Applicants' claimed invention. This amendment is supported by the specification, for example, at page 23 lines 17-19.

Applicants submit that no new matter has been added by this amendment.

II. Rejection Under 35 U.S.C. § 112

The Examiner has rejected claims 1-13 and 32 as indefinite under 35 U.S.C. § 112, second paragraph for the reasons disclosed at page 3 of the Non-Final Office Action. Applicants submit that claims 1-13 and 32 have been cancelled, thus, obviating the Examiner's rejection. Applicants respectfully request the Examiner to withdraw the rejection under 35 U.S.C. § 112, second paragraph.

III. Rejection Under 35 U.S.C. § 102

The Examiner has rejected claims 1-4, 6-13 and 32 as anticipated under 35 U.S.C. § 102(b) over U.S. Patent No. 4,145,254 ("Shepherd") for the reasons disclosed at pages 3-5 of the Non-Final Office Action. Applicants submit that these claims have been cancelled, thus, obviating the Examiner's rejection and respectfully request the Examiner to withdraw the rejection under 35 U.S.C. § 102(b).

IV. Rejection Under 35 U.S.C. § 103

A. The Examiner has rejected claims 1-13 and 32 as obvious under 35 U.S.C. § 103(a) over Shepherd, in view of U.S. Patent No. 5,013,564 ("St. Martin") for the reasons disclosed at pages 5-6 of the Non-Final Office Action. Applicants submit that claims 1-

13 and 32 have been cancelled, thus, obviating the Examiner's rejection and respectfully request the Examiner to withdraw the rejection under 35 U.S.C. § 103(a).

B. The Examiner has rejected claims 36-49 as obvious under 35 U.S.C. § 103(a) over U.S. Patent No. 4,772,558 ("Hammann") for the reasons disclosed at pages 6-9 of the Non-Final Office Action. Applicants respectfully traverse this rejection for at least the following reasons.

To establish a *prima facie* case of obviousness under 35 U.S.C. § 103, the Examiner bears the burden of establishing each of three requirements. *In re Fine* 837 F.2d 1071, 1074, 5 U.S.P.Q.2d 1596, 1599 (Fed. Cir. 1988). First, the Examiner must establish that the references teach or suggest each and every element and limitation recited in the claims. *See* M.P.E.P. § 2143.03. Second, the Examiner must establish that some suggestion or motivation exists, either in the references themselves, or in the knowledge generally available to one of ordinary skill in the art, to modify or combine the references to achieve the presently claimed invention. *See* M.P.E.P. § 2143.01. Third, the Examiner must establish a reasonable expectation of success for the proposed combination or modification. *See* M.P.E.P. § 2143.02. Moreover, each of these requirements must "be found in the prior art, and not be based on applicant's disclosure." M.P.E.P. § 2143. Appealing to "common sense" and "basic knowledge" without any evidentiary support cannot cure any deficiencies in the references. *In re Zurko*, 258 F.3d 1379, 1385, 59 U.S.P.Q.2d 1693, 1697 (Fed. Cir. 2001).

At a minimum, Applicants submit that the Examiner cannot establish that Hammann teaches or suggests each and every element recited in the claims, or that some suggestion or motivation exists, in Hammann, or in the knowledge generally available to one of ordinary skill in the art, to combine or modify the references to achieve the presently claimed invention. *See* M.P.E.P. § 2143.01; M.P.E.P. § 2143.03.

Applicants submit that Hammann fails teaches or suggests, at a minimum, a method of producing a biochemical with the claim limitations of “inoculating with a microorganism a first face of a support means forming a dividing partition defining first and second volumes of a container, said first volume being in communication with the ambient atmosphere via a gas permeable plug.”

Hammann discloses a method and apparatus for culture and detection of microorganisms in body fluids. ('558 at col. 2, ll. 8-11). Hammann also discloses that the sample, suspected of containing a pathogenic microorganism, is inoculated into the liquid medium contained in the first compartment. (*Id.* at col. 3, ll. 39-44). Hammann fails to teach or suggest, however, the claim limitations of “inoculating with a microorganism a **first face** of a support.” (emphasis added). Hammann also fails to teach or suggest the claim limitations of “means forming a dividing partition defining first and second volumes of a container, said first volume being in communication with the ambient atmosphere via a gas permeable plug.”

In contrast to applicants' claimed invention, Hammann support is a free-standing frame 21 formed with trays, that acts as a matrix for the solid agar nutrient material 24. (See *e.g., id.* at col. 2, ll. 63-67). Hammann's dividing wall 13 serves only as a divider (See *e.g., id.* at Fig. 3), and is incapable of supporting a microorganism as it grows. Furthermore, Hammann fails to teach or suggest the claim limitations of “ending access of said microorganism to said first liquid medium and separating said microorganism therefrom by removing a portion of the container which contains said first liquid medium” and ” allowing access to said second liquid medium by said microorganism, and allowing said microorganism to produce said biochemical in its cells or to secrete said biochemical into said second liquid medium, or both.”

In contrast to the procedure taught by Hammann, in Applicants' claimed method a microorganism is inoculated onto the **support** and not into the growth medium. Hence, it is easy to separate the microorganism from the medium when it is desired to change the medium. Moreover, in Hammann the first (liquid) medium is allowed into contact with the second (solid) medium by allowing a breach (a gap between the container cap 23 and the dividing wall 13) between the first and second compartments in the container. (See *e.g., id.* at Fig. 1). Applicants' claimed method, however, maintains the first medium entirely separate from the second medium and the support. The separation between the first volume of the container and the second volume is never breached.

Since Hammann fails to teach or suggest a method of producing a biochemical comprising the claim limitations of "inoculating with a microorganism a first face of a support means forming a dividing partition defining first and second volumes of a container, said first volume being in communication with the ambient atmosphere via a gas permeable plug" the Examiner must establish some motivation to modify the teachings of Hammann. But the Examiner has not done so.

Contrary to the Examiner's assertion on page 8 of the Non-Final Office Action, it is not merely a matter of "judicious selection and routine optimization" to achieve the missing claim limitations that Hammann fails to teach or suggest, since only result-effective variables can be optimize. (See M.P.E.P. § 2144.05 (II) (B)). Accordingly, "a particular parameter must first be recognized as a result-effective variable, *i.e.*, a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation." (*Id.*). In this case, as noted by the Examiner on page 8 of the Non-Final Office Action, "Hammann does not teach said first volume being in

communication with the ambient atmosphere via a gas permeable plug.” Moreover, Hammann does not teach or suggests that this or the other claim limitations noted by the Examiner are result –effective variables.

Accordingly, Applicants submit that the Examiner cannot satisfy the burden of establishing a *prima facie* case of obviousness with respect to claims 36-49 of the presently claimed invention, and respectfully requests that the § 103 rejection be withdrawn.

V. Conclusion

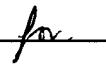
In view of the foregoing remarks, Applicants submit that this claimed invention is neither anticipated nor rendered obvious in view of the prior art references cited against this application. Applicants therefore respectfully request reconsideration of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account no. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.



By: Reg. No. 43,662 
Jeffrey A. Berkowitz
Reg. No. 36,743

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